

1. A method of test strip qualification, said method comprising:
providing a test strip comprising an assay reaction area, a first control reaction area and a second control reaction area;
obtaining PT results for each reaction area;
comparing results from said first control area to a first control qualification criteria and results from second control area to a second control qualification criteria, wherein said first control qualification criteria comprises an upper limit and a lower limit, said first control upper limit being about 1.9 INR and said first control lower limit being about 0.60 INR; and
outputting a message to a user indicating test strip reliability.
2. The method of claim 1, wherein said second control qualification criteria comprises an upper limit and a lower limit, said upper limit being dependent upon assay reaction area PT results, said lower limit having first and second sections dependent upon assay reaction area PT results.
3. The method of claim 2, wherein said second control criteria upper limit comprises a line function and said second control criteria lower limit comprises a line function.
4. The method of claim 3, wherein said line functions are expressed as:
 $y = mx + b$,
wherein y represents INR results obtained for said second control and x represents INR results obtained for said assay reaction area;
wherein $m \approx 0.56$ to 0.58 and $b \approx 0.90$ for said upper limit; and
wherein $m \approx 0.36$ and $b \approx 0.37$ to 0.38 for said lower limit.

5. A method of test strip qualification, said method comprising:

providing a test strip comprising an assay reaction area, a first control reaction area and a second control reaction area;

obtaining PT results for each reaction area;

comparing results from the first control area to first control qualification criteria and

comparing results from second control area to second control qualification criteria, wherein said

second control qualification criteria comprises an upper limit and a lower limit, each being

dependent on assay reaction area PT results; and

outputting a message to a user indicating test strip reliability.

6. The method of claim 5, wherein said second control criteria upper and lower limit functions comprise line functions.

7. The method of claim 6, wherein said line functions are expressed as:

$$y = mx + b; \text{ and}$$

wherein y represents INR results obtained for said second control and x represents INR results obtained for said assay reaction area;

wherein $m \approx 0.56$ to 0.58 and $b \approx 0.90$ for said upper limit; and

wherein $m \approx 0.36$ and $b \approx 0.37$ to 0.38 for said lower limit.

8. The method of claim 5; wherein said first control qualification criteria comprises an upper limit and a lower limit, said first control upper limit being about 1.9 INR and said first control lower limit being about 0.60 INR.

9. A method of test strip qualification comprising:
providing a test strip comprising an assay reaction area, a first control reaction area and a second control reaction area;
obtaining PT results for each reaction area; and
comparing test strip results from said first control reaction area to a first set of criteria substantially and comparing results from said second control reaction area to a second set of criteria substantially as represented in figure 4.
10. The method of claim 9, wherein said first set of criteria are substantially comprise an upper limit of about 1.9 INR and a lower limit of about 0.60 INR.
11. A system programmed to operate according to a method selected from a group of methods consisting of the test strip qualification methods of claims 1-10.
12. The system of claim 11, further comprising a test strip comprising an assay reaction area, a first control reaction area and a second control reaction area.
13. A computer-readable medium embodying a program to direct a system to perform a method selected from a group of methods consisting of the test strip qualification methods of claims 1-10.
14. A computer-readable medium containing data representing sample results, wherein said data is made by a method selected from a group of methods consisting of the test strip qualification methods of claims 1-10.